

II. REMARKS

PRELIMINARY REMARKS

Claims 1-36 are previously cancelled. Claims 37-54 are pending. Claims 37 and 48-54 are rejected, claims 38-47 are objected to for depending from a rejected base claim.

Amendment of the Specification

The amendment to the specification at page 1, line 3 corrects the priority claim of the present application. The paragraphs on pages 6 and 14 are amended to correct and update references to U.S. applications. The paragraph beginning on page 32, line 3, is amended to identify the SEQ ID NOs. of the disclosed primer sequences. The paragraph on page 74, line 12, is replaced by the new paragraph, which identifies the location of the deposit and that the deposit was made under the terms of the Budapest Treaty, no new matter is added.

The descriptions of Figures 1-6, 7-1, 7-2, 8, 16, and 17, which disclose DNA and/or amino acid sequences, are amended to identify the SEQ ID NOs. of the disclosed sequences.

The descriptions of Figures 4-6 are further amended to indicate that the figures depict the DNA and amino acid sequences of the disclosed gamma 4 heavy chain polypeptides.

The description of Figure 7-1 is further amended to indicate that the figure depicts nucleic acid sequences of amplification primers useful in the invention, in accord with the information presented in the figure.

The description of Figure 1 on page 11 incorrectly describes the amino acid and nucleotide sequences of the heavy chain variable region of CE9.1 shown in Figure 1 as “the light variable domain of CE9.1.” Likewise, the description of Figure 2 on the same page incorrectly describes the amino acid and nucleotide sequences of the light chain variable region of CE9.1 shown in Figure 2 as “the heavy variable domain of CE9.1.” The correct identities of the amino acid and nucleotide sequences of the variable regions of the light and heavy chains of CE9.1 are readily identifiable from consideration of the respective lengths of the disclosed sequences - the light chain polypeptide has only 233 amino acids (see Figure 3 and SEQ ID NOs: 5 and 6),

whereas the heavy chain polypeptide has 467 amino acids (see Figure 4 and SEQ ID NOs: 7 and 8). Furthermore, from comparison of the amino acid and nucleotide sequences of the variable regions shown in Figure 1 (SEQ ID NOs: 1 and 2) to the initial sequences of Figures 3 and 4, it would be clear to one skilled in the art that the sequences shown in Figure 1 (SEQ ID NOs: 1 and 2) are the sequences of the variable region of the heavy chain polypeptide that is shown in Figure 4 (SEQ ID NOs: 7 and 8). Similarly, the sequences shown in Figure 2 (SEQ ID NOs: 3 and 4) are clearly those of the variable region of the light chain polypeptide that is shown in Figure 3 (SEQ ID NOs: 5 and 6).

Replacement Drawings

Replacement drawing sheets with Figures 1-6, 7-1, 7-2, 8, 16, and 17 are submitted herewith which identify the SEQ ID NOs. of the disclosed sequences. The revised figures do not include new matter - apart from the insertion of the SEQ ID NOs., the content of the revised figures is the same as that of the figures they replace.

Additionally, the nucleotide and amino acid sequences of the heavy chain variable region shown in Figure 1 are amended by inserting the nucleotide triplet “TCA” at the 3’ end of the nucleotide sequence, and the symbol “S” designating the amino acid serine at the end of the corresponding amino acid sequence. The 3’ terminal codon was inadvertently omitted from the sequence shown in Figure 1, but is disclosed as terminal nucleotides 418-420 of the nucleotide sequence encoding the variable region in the full length heavy chain sequences shown in Figures 4, 5, and 6. One of ordinary skill in the art at the time of filing would readily recognize the omission of the nucleotide triplet “TCA” from the 3’ end of the nucleotide sequence encoding the CE9.1 variable region shown in Figure 1, because the human gamma 4 constant region shown in Figure 4 was a well-characterized polypeptide that was known to have the amino acid sequence Ala – Ser – Thr at its amino terminus, as shown in GenBank protein database locus no. P01861 (previously submitted). One of ordinary skill in the art would therefore recognize that the alanine residue encoded by nucleotides 421-423 is the first residue at the amino terminus of human gamma 4 constant region shown in Figure 4, and that the serine residue encoded by nucleotides 418-420 (TCA) is the terminal residue of the variable region in Figure 4. The

nucleotide triplet “TCA” is also shown as the 3’ terminal codon of the nucleotide sequence encoding the CE9.1 variable region in SEQ ID NO: 15 of the sequence listing of parent U.S. Patent Application No. 08/476,237, filed on June 7, 1995, and issued as U.S. Patent No. 5,756,096, the contents of which are incorporated into the present application.

Also, the amino acid shown at position 119 of Figure 1 is corrected to indicate valine (V). As described in the specification, the nucleotide sequence shown in Figure 1 is obtained by cloning of a heavy chain variable region (see page 32, lines 19-26; page 35, lines 3-9; page 35, line 23 through page 36, line 9). The amino acid sequence is then derived from the sequence of the cloned nucleic acid. The skilled person would know that the nucleic acid codon sequence GTC encodes valine, and would therefore recognize that the serine (S) shown over the codon GTC at position 119 in original Figure 1 is an error and that the correct amino acid that is encoded by the disclosed nucleic acid sequence is valine. The amendment of the sequence shown in Figure 1 corrects an inadvertent error in the nucleotide sequence encoding the heavy chain variable region of CE9.1, and does not add new matter.

Amendment of the Sequence Listing

Referring to the substitute Sequence Listing, SEQ ID NO: 1, which corresponds to Figure 1, is amended by adding the nucleotides TCA, which encode serine, to the 3’ end of the sequence. SEQ ID NO: 2 of the sequence listing, which is the amino acid sequence encoded by the nucleotide sequence of SEQ ID NO:1, is amended by adding serine to the carboxy terminal end of the sequence. As discussed above in regard to the amendment of Figure 1, the nucleotides added to SEQ ID NO:1 are disclosed in Figure 4 of the present application, and were disclosed in SEQ ID NO: 15 of the sequence listing of parent U.S. Patent Application No. 08/476,237, filed on June 7, 1995, and issued as U.S. Patent No. 5,756,096, the contents of which are incorporated into the present application. The nucleotides added to the 3’ end SEQ ID NO:1 and the amino acid added to the C terminus of SEQ ID NO:2 were inadvertently omitted from the sequence listing, and their inclusion in the sequence listing by the foregoing amendment is a correction that does not add new matter.

A copy of a substitute sequence listing in paper form in compliance with 37 C.F.R. §§

1.822 is submitted herewith. Also, the applicants submit a copy of the substitute sequence in computer readable format herewith.

Double patenting rejections

Claims 37, 48 and 49 are rejected on the ground of non-statutory obviousness-type double patenting over claims 1, 5-8 and 10 of U.S. Patent No. 5,750,105. Applicant herewith submits a terminal disclaimer in view of U.S. Patent No. 5,750,105, therefore, the rejection is now moot.

Likewise, claims 37 and 48-54 are provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 37 and 47-50 of co-pending U.S. Application No. 10/211,357. Although this is a provisional rejection because the 10/211,357 application has not issued as a patent (notice of allowance mailed August 9, 2007), applicant herewith submits a terminal disclaimer in view of U.S. Application No. 10/211,357, therefore, the rejection is now moot.

Claim objections

Claims 38-47 are objected to for depending from a rejected base claim. In view of the terminal disclaimers filed, described above, the rejection of the base claim is now moot. Accordingly, the objection to claims 38-47 is also now moot.

III. CONCLUSION

For the reasons stated above, applicant believes that this application is in condition for allowance and respectfully requests the examiner issue a notice of allowance. If the examiner identifies any points that he feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Please charge any fees or credit any overpayments associated with the submission of this response to Deposit Account Number 03-3975.

Respectfully submitted,

/ thomas a cawley jr /

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